K083721

JAN - 8 2009

510(k) Summary

Submitter of the Application

Company:	River's Edge Pharmaceuticals, LLC 5400 Laurel Springs Pkwy Building 500 Suwanee, GA 30024
Phone:	(770) 886-3417
Fax:	(770) 886 3917

Contact for the Application

Company:	Gorbec Pharmaceutical Services Inc. 2445 S. Alston Ave. Durham NC 27713
Contact Name:	Sandra R. Kircus
Phone:	(919) 281 4080
Fax:	(919) 281 4077
Email:	sandra.kircus@gorbec.com

Trade Name

Zenieva

Common name

Hydrogel wound dressing

Device Classification

21 CFR 878.4022 "Dressing, Wound, Hydrogel"
Class I Non-Exempt, NAE.

Substantial Equivalence / Predicate Device

River's Edge Pharmaceuticals, LLC believes the modification submitted for Zenieva is substantially equivalent to the approved device currently cleared under 510K Number K082865, approved 23 October 2008.

Device Description and Design

Zenieva is a non-sterile, semi-viscous emulsion intended for topical application. It is presented for prescription (requires a physician diagnosis of disease state) use. The product is formulated as an oil-in-water emulsion containing a cross-linked polyacrylic acid polymer, natural gum, and cellulose as thickening agents. The oil composition of Zenieva is composed of glyceride, squalane, lecithin, and fatty acids.

Intended Use of the Device

Zenieva is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. Zenieva helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

This intended use is identical to the intended use previously cleared for Zenieva. Therefore, there is no issue with determining differences in the safety and efficacy as related to the predicate device.

Technological Comparison to Device Predicate Device

The modification to Zenieva does not change the chemical composition, intended indications for use, physical properties, or claims.

Non-Clinical Performance Data

Performance testing for Zenieva was conducted and assessed. This data was compared to the approved device; the modification was determined to be a satisfactory change with no compromise in the safety or efficacy of the product.

Conclusion

The product's ingredients and performance characteristics have remained unchanged. Tests and performance data are satisfactory and indicate the product remains safe, effective, and substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 5 - 2009

River's Edge Pharmaceuticals, LLC
% Gorbec Pharmaceutical Services, Inc.
Sandra R. Kircus, Ph.D.
Regulatory Affairs Manager
2445 South Alston Avenue
Durham, North Carolina 27713

Re: K083721
Trade/Device Name: Zenieva
Regulation Number: 21 CFR 878.4022
Regulation Name: Hydrogel wound dressing and burn dressing
Regulatory Class: I
Product Code: NAE
Dated: January 8, 2009
Received: January 8, 2009

Dear Dr. Kircus:

This letter corrects our substantially equivalent letter of January 8, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276 - 0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K083721

Device Name: Zenieva Wound Dressing

Indications For Use:

Zenieva is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. Zenieva helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083721

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)